



Department of Health and Human Services
American Recovery and Reinvestment Act
Supporting Comparative Effectiveness Research



Office of the Secretary: Comparative Effectiveness Research

The Department of Health and Human Services (HHS) is currently developing a plan and a corresponding funding allocation for dollars appropriated to the Agency for Healthcare Research and Quality (AHRQ) for comparative effectiveness research. The American Recovery and Reinvestment Act (Recovery Act) appropriated \$1.1 billion for comparative effectiveness research, of which \$300 million is for AHRQ, \$400 million is for the National Institutes of Health, and \$400 million is for allocation at the discretion of the Secretary.

This implementation plan focuses on the \$400 million to be allocated by AHRQ at the discretion of the Secretary.

A. Funding Table

(Dollars in Millions)

	Total Appropriated	Planned Obligations FY 2009	Planned Obligations FY 2010
Comparative Effectiveness Research	\$400.0	*	**
Total	\$400.00		

*Thus far, a total of \$2.6 million is planned for obligation in FY 2009: \$1.5 million has been obligated to fund an Institute of Medicine study on comparative effectiveness research and \$1.1 million has been apportioned for obligation for logistical and research support for the Federal Coordinating Council for Comparative Effectiveness Research.

**HHS is currently developing a plan that specifies the kind and scope of activities that will be funded to achieve the program's objectives. FY 2010 planned obligations are not yet determined.

B. Objectives

The overarching goal of this program is to improve health outcomes by providing evidence to enhance medical decisions made by patients and their medical providers. This goal is achieved by conducting and supporting comparative effectiveness research. The Department of Health and Human Services uses the definition of comparative effectiveness research as set forth by the Federal Coordinating Council for CER:

Comparative effectiveness research is the conduct and synthesis of systematic research comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions. The purpose of this research is to inform patients, providers, and decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances. To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations. Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, behavioral change strategies, and delivery system interventions. This research necessitates the



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development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness.

Systematic research methods can include randomized controlled trials, meta-analyses, observational cohort analyses, and other new and emerging methodologies. Comparative effectiveness studies may compare similar treatments, such as competing drugs, or analyze very different approaches, such as surgery and drug therapy. Evaluation of treatments includes any potential medical intervention under consideration, whether prognostic, preventive, diagnostic, therapeutic, or palliative. Comparative effectiveness research may also address public health or systems interventions that affect health outcomes. Comparative effectiveness research is designed to inform patient and clinician decisions relevant to the unique circumstances of individual patients.

AHRQ will spend appropriated funds to research and provide information on the relative strengths and weaknesses of various medical interventions. Such research will give clinicians and patients valid information with which to make decisions that will improve the performance of the U.S. health care system. AHRQ's comparative effectiveness research will support HHS strategic plan goal 1¹ : improve the safety, quality, affordability and accessibility of health care, including behavioral health care and long-term care.

C. Activities

HHS is currently developing a plan that specifies the kind and scope of activities that HHS will fund to achieve the program's objectives. HHS is considering various approaches for this program to complement the funding in AHRQ and NIH. Consistent with the Recovery Act, funds will be used to accelerate the development and dissemination of research assessing the comparative effectiveness of health care treatments and strategies through efforts that conduct, support, or synthesize research that compares the clinical outcomes, effectiveness, and appropriateness of items, services and procedures that are used to prevent, diagnose, or treat diseases, disorders and other health conditions. The Secretary will also allocate funds to encourage the development and use of clinical registries, clinical data networks, and other forms of electronic health data that can be used to generate or obtain outcomes data.

In addition, the Recovery Act instructs the Secretary to enter into a contract with the Institute of Medicine (IOM) for no more than \$1.5 million. The IOM is to produce and submit a report to Congress and the Secretary no later than June 30, 2009 recommending priorities for the comparative effectiveness research to be conducted or supported with Recovery Act funds for comparative effectiveness research allocated at the Secretary's discretion. On February 28, 2009, HHS informed the Appropriations Committees of the House and of the Senate of the planned use of \$1.5 million to contract with the IOM for this study. The Recovery Act also requires HHS, jointly with the directors of AHRQ and NIH, to provide an operating plan to

¹ HHS Strategic Plan Goals and Objectives - FY 2007-2012 available at http://www.hhs.gov/strategic_plan/



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Congress before obligating any Recovery Act funds for comparative effectiveness research.

Section 804(f) of the Recovery Act addressed the Federal Coordinating Council for Comparative Effectiveness Research and instructed the Secretary to make no more than \$4 million available to the Council for staff and administrative support. On April 23, 2009, HHS informed the Appropriations Committees of the House and of the Senate of the planned use of \$1.1 million for logistical and research support for the Federal Coordinating Council in FY 2009.

D. Characteristics

HHS is currently developing a plan that specifies the financial award mechanisms that HHS will use to execute the program and the recipients and beneficiaries of the program funds. HHS is considering various award mechanisms, such as grants, contracts, and cooperative agreements. HHS is also considering the appropriate intended recipients for each type of award, such as researchers, academic institutions, states, community-based organizations, national organizations, and private or non-profit organizations. Organizations could include community-based health care delivery organizations, provider organizations, payers, delivery systems, and other organizations with capacity to conduct or support CER.

E. Delivery Schedule

HHS will develop a schedule with milestones and planned delivery dates for major phases of the program's activities. As the Recovery Act requires, HHS will submit an operating plan for this program to the House and Senate Appropriation Committees prior to obligating Federal funds and not later than July 30, 2009.

F. Environmental Review Compliance

HHS will ensure that it complies with environmental statutes if program activities require an environmental review according to those statutes. The OS does not anticipate any construction or renovation funded under this activity.

The environmental impact for acquisition of IT and other products and equipment will be mitigated by compliance with criteria described in Executive Order 13423 and the HHS Affirmative Procurement Plan (APP) and written guidance to this effect will be provided to grantees as appropriate.

G. Measures

HHS is working to develop cross-cutting outcome measures for comparative effectiveness research activities across the Department. Initial outcome measures will be developed by December 1, 2009. In addition, the measures below will be reported quarterly and help HHS track progress toward the program's goals and objectives. Planned measures include the following and most of these measures will be reported quarterly. Targets may change and additional measures may be developed given that priorities and a spending plan are not yet finalized.



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Output Measure	FY 2009 Target	FY 2010 Target
Number of Council Meetings	14	6
Number of people and organizations who provide written or verbal comments for Council's consideration	300	100

H. Monitoring and Evaluation

All Recovery Act programs will be assessed for risk and to ensure that appropriate internal controls are in place throughout the entire funding cycle. An internal control is an accounting procedure or system designed to promote efficiency, assure the implementation of policy, and safeguard assets. These assessments will be done consistent with the statutory requirements of the Federal Manager's Financial Integrity Act and the Improper Payments Information Act, as well as OMB's circular A-123 "Management's Responsibility for Internal Control".

HHS is developing a process for periodic review of the program's progress to identify areas of high risk, high and low performance, and any plans for longer term impact evaluation.

I. Transparency

The Office of the Secretary (OS) will be open and transparent in all of its grant competitions that involve spending of Recovery Act funding consistent with statutory and OMB guidance.

HHS will ensure that recipient reporting required by Section 1512 of the Recovery Act and OMB guidance is made available to the public on Recovery.gov by October 10, 2009. HHS will inform recipients of their reporting obligation through standard terms and conditions, grant announcements, contract solicitations, and other program guidance. HHS will provide technical assistance to grantees and contractors and fully utilize Project officers to ensure compliance with reporting requirements. HHS and OS are still finalizing the process surrounding recipient-level reporting to the public. Once the process is finalized the information will be shared with recipients.

J. Accountability

To ensure that managers are held to high standards of accountability in achieving program goals under the Recovery Act, HHS will build on and strengthen existing processes. Senior OS officials will meet regularly with senior Department officials to ensure that projects are meeting their program goals, assessing and mitigating risks, ensuring transparency, and incorporating corrective actions. Corrective actions are steps taken to identify and eliminate the causes of a problem, thus preventing their recurrence. The personnel performance appraisal system will also incorporate corrective actions. The personnel performance appraisal system will also incorporate Recovery Act program stewardship responsibilities for program and business function managers.



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K. Barriers to Effective Implementation

One potential barrier/risk to effective implementation is funding projects that do not meet the needs of stakeholders. To minimize this risk, HHS will continue to increase the transparency and explicit process for comparative effectiveness research and will continue to engage stakeholders throughout the research process.

L. Federal Infrastructure

The OS does not anticipate any construction or renovation funded under this activity. However, HHS will ensure that it complies with energy efficiency and green building requirements, if applicable.